

Notice of Intent to Certify Sole Source

To: Interested Parties

From: Stacy Baldwin
Agency Procurement Officer

Date: May 9, 2016

Re: Sole Source Certification Number **SS5031** for **Geenius™ HIV 1/2 Complete System, HIV 1/2 Supplemental Assay, and Controls intended for monitoring system**

Contact Email Address: solesource@umc.edu

Sole Source Certification Award Details

Regarding UMMC Sole Source Certification Number **SS5031** for **Geenius™ HIV 1/2 Complete System, HIV 1/2 Supplemental Assay, and Controls intended for monitoring system**, please be advised that UMMC intends to award the purchase of the **Geenius™ HIV 1/2 Complete System, HIV 1/2 Supplemental Assay, and Controls intended for monitoring system** to **Bio-Rad Laboratories, Inc. (Bio-Rad)** as the sole source provider of the **Geenius™ HIV 1/2 Complete System, HIV 1/2 Supplemental Assay, and Controls intended for monitoring system**.

UMMC issues this notice in accordance with Mississippi state law, policy, and procedures for sole source procurements.

Sole Source Criteria

1. Where the compatibility of equipment, accessories, or replacement parts is the paramount consideration (and manufacturer is the sole supplier).
2. Where a sole supplier's item is needed for trial use or testing.
3. Where a sole supplier's item is to be required when no other item will service the needs of UMMC.

Schedule

Task	Date
First Advertisement Date	May 9, 2016
Second Advertisement Date	May 16, 2016
Response Deadline from Objectors	May 24 2016, at 3:00 p.m. Central Time
Notice of Award/No Award Posted	Not before May 25, 2016

Project Details

1. Describe the commodity that the agency is seeking to procure:

The University of Mississippi Medical Center (UMMC) seeks to purchase the Geenius™ HIV 1/2 Complete System, HIV 1/2 Supplemental Assay, and Controls intended for monitoring system.

The Geenius™ System and its associated HIV1/2 supplemental assay is the confirmatory test done on all patients whose initial screening test is positive for HIV. Currently this confirmation is done in-house by a different Bio-Rad assay, but this assay is being phased out and will not be available after July 2016. This test confirms HIV infection for positive screens and differentiates HIV1 from HIV2, since the two types have markedly different clinical courses and treatment implications.

UMMC serves a patient population with a high prevalence of HIV, and accurate, rapid diagnosis is key to ensuring proper care and limiting spread of the infection within the community. Sending out this test to a reference lab would be at a higher cost, and delay results by several days. This would likely result in newly diagnosed patients being lost to follow-up, or getting started on therapy later than would be optimal. Rapid result turnaround time is important to public safety and quality of patient care.

2. Explain why the commodity is the only one (1) that can meet the needs of the agency:

The Bio-Rad Geenius™ HIV 1/2 Supplemental Assay Rapid test are the only tests in the USA to offer detection and differentiation of HIV-1 and HIV-2 antibodies and are proprietary to the system.

3. Explain why the source is the only person or entity that can provide the required commodity:

Bio-Rad is the sole manufacturer, distributor and supplier in the United States of the Geenius™ HIV 1/2 Complete System, HIV 1/2 Supplemental Assay, and Controls intended for monitoring system, except that Bio-Rad has certain very limited agreements with distributors to sell directly to blood banks, the U.S. Government, and under the TXMAS state wide contract. These distributors are not authorized to sell to any customers other than to blood banks, the U.S. government, and under the TXMAS state wide contract.

See supporting letter from **VENDOR**, Attachment A.

4. Explain why the amount to be expended for the commodity is reasonable:

The estimated amount to be expended is for the purchase of the capital Geenius™ HIV 1/2 Complete System, HIV 1/2 Supplemental Assay, and Controls intended for monitoring system:

Geenius™ HIV 1/2 Complete System -	\$ 4875.00
HIV 1/2 Supplemental Assay, and Controls	\$74500.00

This amount is within the expected price range for these products.

5. Describe the efforts that the agency went through to obtain the best possible price for the commodity:

Through market intelligence, UMMC was able to negotiate best pricing for these products. All applicable discounts were explored and applied.

Submission Instructions and Format of Response from Objecting Parties

Interested parties who have reason to believe that the **Geenius™ HIV 1/2 Complete System, HIV 1/2 Supplemental Assay, and Controls intended for monitoring system** (hereafter, “Products”) should not be certified as a sole source should provide information in the Vendor Form for the State to use in determining whether or not to proceed with awarding the sole source to **Bio-Rad Laboratories, Inc.**

The Vendor Form may be found at <http://www.dfa.state.ms.us/Purchasing/documents/ObjectiontoSoleSourceDetermination.pdf>.

Objections must include the certification in Attachment B.

Comments will be accepted at any time prior to Tuesday, May 24, 2016, at 3:00 p.m. (Central Time) to solesource@umc.edu. Responses may be delivered via email to solesource@umc.edu. UMMC WILL NOT BE RESPONSIBLE FOR DELAYS IN THE DELIVERY OF RESPONSES. It is solely the responsibility of the Interested Parties that responses reach UMMC on time. Responses received after the deadline and responses that lack all required information will be rejected. UMMC reserves the right to inspect Interested Party’s commodity for comparison purposes.

If you have any questions concerning the information above or if we can be of further assistance, please contact solesource@umc.edu.

Attachment A: Vendor Correspondence

Attachment B: Objection Certification

Exhibit A



**Bio-Rad
Laboratories**

Diagnostics Group
6565 185th Ave NE
Redmond, WA 98052
Ph: 1-800-666-8111
Fax: 1-425-498-1620

April 20, 2016

University of Mississippi Medical Center
1410 East Woodrow Wilson Ave
Jackson, MS 39216
Sold-to: 1001719
Ship-to: 1001719

RE: Sole Source Letter

I am writing this letter to confirm for you that Bio-Rad Laboratories, Inc. ("Bio-Rad") is the sole manufacturer, distributor and supplier in the United States of the products shown below, except that Bio-Rad has certain very limited agreements with distributors to sell directly to blood banks, the U.S. Government, and under the TXMAS state wide contract. These distributors are not authorized to sell to any customers other than to blood banks, the U.S. government, and under the TXMAS state wide contract.

72461	Geenius™ HIV 1/2 Supplemental Assay
92465	Geenius™ Reader
92052	Geenius™ Computer
12000211	Printer
12000019	Barcode Scanner

The Bio-Rad Geenius™ HIV 1/2 Supplemental Assay and the Multispot® HIV-1/ HIV-2 Rapid test are the only tests in the USA to offer detection and differentiation of HIV-1 and HIV-2 antibodies.

Bio-Rad Laboratories, Inc. is a Multinational Manufacturer and Distributor of Life Science research products, Clinical Diagnostics and Analytical Instrumentation, based in Hercules, California.

Sincerely,


Digitally signed by Janette Stockert
DN: cn=Janette Stockert, o=Bio-Rad, ou=Global,
ou=North America, ou=US,
ou=Washington, ou=Redmond,
ou=US, ou=United States,
ou=Janette Stockert
Date: 2016.04.20 16:53:01 -0700

Janette J. Stockert
Contract Administration Supervisor
Government Contracts / Paralegal

JJS:cc

Attachment B

**SUBMITTED IN RESPONSE TO
Sole Source Certification No. SS5031
Accepted until May 24, 2016, at 3:00 p.m.**

I certify that the information contained in this objection is true and accurate to the best of my knowledge. I understand that UMMC will investigate all statements made in this objection and that any false or misleading information provided may result in adverse action.

Objector Name
Objector's title

Date